Testimony of

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Before the

Committee on Energy and Commerce

U.S. House of Representatives

"American Lives Still at Risk: When Will FDA's Food Protection Plan be Fully Funded and Implemented?"

June 12, 2008

Mr. Chairman, members of the Committee: it is a pleasure to have the opportunity to speak before you today to review the findings of the Report of the FDA Science Board's Subcommittee on Science and Technology, on which I was a member. In the second part of my testimony, I would like to expand my remarks beyond the report to deal at a more general level with the ability of FDA to identify and control risks in our U.S. food supply.

The Subcommittee's report was entitled "FDA Science and Mission at Risk," correctly emphasizing the critical nature of the current situation at FDA. In discussing food safety, the report concluded that "FDA does not have the capacity to ensure the safety of food for the nation. Crisis management in FDA's two food safety centers, Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM), has drawn attention and resources away from FDA's ability to develop the science base and infrastructure needed to efficiently support innovation in the food industry, provide effective routine surveillance, and conduct emergency outbreak investigation activities to protect the food supply."** I would strongly support these conclusions.

As highlighted in the Subcommittee report, the current situation reflects decades of neglect of CFSAN and CVM's resource needs. Since 2003, CFSAN's workforce has declined from 950 FTE to 771 FTE, at a time when there have been increasing demands on the agency. This includes demands brought on by an increasingly complex food supply, with rapidly expanding internationalization of markets, as well as increasing regulatory responsibilities related to new legislative mandates. Problems in both CFSAN and CVM have been further exacerbated by major outbreaks and recalls, which, of necessity, divert resources away from "routine" scientific, surveillance, and regulatory activities.

In the absence of a clearly articulated vision for food safety in this country, it is difficult to come up with estimates for what it will cost to optimize the FDA food safety program. However, in response to a specific request of representatives Dingell, Waxman, Stupak, and Pallone, our Subcommittee developed cost estimates for beginning the rebuilding process in the agency; responses were submitted by Dr. Cassell on February 25 of this year. To summarize, our Subcommittee estimates called for an increase in the annual budget of food-related components of FDA of approximately $128 million for FY2009, with a cumulative increase of $755 million in annual budget by 2013. This figure includes $350 million to strengthen imports and $100 million to strengthen work with nutritional supplements, animal health, and cosmetics. Separate from this total is an additional $450 million cumulative 5-year increase in annual budget for enhancement of FDA Information Technology, an enhancement which is critical for FDA to be able to deal with the massive data flows necessary for its activities, including appropriate surveillance and food protection.***

Food safety remains a critically important area of concern to the U.S. public. While attention always tends to focus on the latest outbreak, it is perhaps most concerning, from an epidemiologic standpoint, that reported incidence rates for the major foodborne pathogens (based on 2007 FoodNet data) have remained relatively constant during the past several years, with some actual increases. This follows initial declines in incidence rates seen after implementation of the USDA HACCP rules in 1995, suggesting that the impact of these landmark regulatory changes over a decade ago has "leveled off," and underscoring the need for new and innovative approaches to protect the health of the American people.

FDA, with responsibility for overseeing an estimated 80% of the nation's food supply, must take the major leadership role in the development and implementation of such new approaches. There is a broad consensus that the agency must develop a pro-active, risk-based (and science-based) preventive approach to food safety. Some of the key elements of such an approach have been articulated by the agency, with the announcement of their Food Protection Plan. However, questions remain about implementation, and about the extent of the FDA vision. I would highlight three key issues:

1) **Development of a risk- and science-based approach to prevention requires science**. Going beyond laboratory science, there is a need for high quality surveillance, both microbiologic and epidemiologic, to clearly identify and delineate problem areas. This, in turn, must be combined with a strong analytic capacity, both to guide the original data collection and to "make sense" of the data when they are collected. In this regard, many of the European countries (such as the Netherlands and Denmark) are well ahead of us, having in place well-designed surveillance systems that are used to regularly "tweak" the approaches and focus areas

of the associated food safety regulatory agencies. Development of public health-based performance standards, which, long-term, are a critical element of a risk-based prevention system, requires an even higher level of sophistication in surveillance and analysis. Unfortunately, the capacity at FDA for such analysis is limited, and there is at best a clouded vision of what is needed for actual implementation of such systems.

2) No matter how good the science, **the agency will not be able to move forward in the absence of an appropriate legislative mandate**. In particular, if we are to develop performance standards, there must be a regulatory structure in place that can make appropriate use of such standards as part of a flexible, risk-based performance system. The legislation before this committee moves in this direction, and I applaud these efforts.

3) And, as previously noted, **there is a need for a substantial increase in the budgets for CFSAN and CVM.** The estimates provided by our subcommittee are a starting point: the actual amounts necessary will almost certainly change, dependent on the extent of the agency's vision, and their approaches to implementation. In the long run, prevention is unquestionably cost-effective. However, we have a lot of rebuilding to do before we can begin to realize such cost savings.

FDA science is at a critical juncture, with the negative impact of declining resources being felt perhaps most strongly in the food safety area. I would urge your committee to work to rebuild this resource base, and provide the necessary underlying legislative mandate, as part of an ongoing effort to define and implement a national vision for the future of food safety.

* Dr. Morris is Director of the newly established Emerging Pathogens Institute (EPI) at the University of Florida, Gainesville, where he is also a Professor of Medicine (Infectious Diseases). From 1994-96, Dr. Morris worked with the Food Safety Inspection Service, USDA, on development of the new HACCP regulations, and was instrumental in the establishment of FoodNet, the national surveillance system for foodborne illness. He has served on four National Academy of Sciences expert committees dealing with food safety, and currently serves on the Institute of Medicine's Food and Nutrition Board. Most recently, Dr. Morris served as a member of the FDA Science Board's Subcommittee on Science and Technology, which was responsible for the February, 2008 report "FDA Science and Mission at Risk."

** Report of the Subcommittee on Science and Technology, FDA Science and Mission at Risk, November, 2007, p.3

*** FDA Science and Mission at Risk. Estimated Resources Required for Implementation. Submitted by Gail Cassell, PhD, on behalf of the Subc0mmittee and its Members. February 25, 2008.